EXHIBIT F

BRIEF DESCRIPTION OF ACTIVITIES
DURING REGULATORY REVIEW PERIOD FOR FACTIVE®

IND Chronology

August 6, 1997	IND 53,908 filed with FDA.
August 13, 1997	FDA acknowledgement of receipt of IND, assignment of IND number.
August 29, 1997	Comments from FDA as review team completes 30-day review period. Request for teleconference.
August 29, 1997	FDA fax with microbiologist's comments on Etest
September 3, 1997	FDA notification "study is safe to proceed".
September 4, 1997	Serial No. 001: Submit Information Amendment: CMC data to support the physical/chemical characterization of the drug substance. Also submitted one month stability data for drug product.
September 25, 1997	FDA response to questions in the IND cover letter and additional comments regarding IND.
September 26, 1997	Serial No. 002: Submit new protocols: modifications to synopses submitted in IND for Studies 001, 002 and 003.
October 1, 1997	Fax to FDA: overview of Phase I studies data to date
October 20, 1997	Serial No. 003: Submit Protocol Amendment: Change in Protocol (Study 004); Response to FDA Request for Information (reply to Aug 29 fax).
November 14, 1997	Serial No. 004: Submit Information Amendment: Clinical: response to request to include women in Phase I studies Pharm/Tox: submit two 13-week study reports (1-rat/1-dog)

December 4, 1997	Serial No. 005: Submit CMC Information Amendment: change in formulation of SB-265805-S capsules, ofloxacin tablets, and placebos for both study medications.
December 22, 1997	Serial No. 006: Submit Protocol Amendment for new investigators for studies 001, 002, 003 and change in protocol for study 004.
January 20, 1998	Serial No. 007: Protocol amendment for new investigators for studies 001, 002 and 003. Submit final complete report of Phase I pharmacology study (No. 1405/32).
February 17, 1998	New USAN (US Adopted Name) Application
February 27, 1998	Serial No. 008: Submit final reports for four microbiology studies, five assay development studies, one MTD study in dogs and two clinical reports for Phase I protocols.
March 6, 1998	Serial No. 009: Protocol amendment regarding addition of sub-investigators and changes to protocol 003.
March 16, 1998	Discussion with FDA project manager regarding End of Phase II meeting briefing document.
March 31, 1998	Serial No. 010: Submit change in protocol for Study 002, addition of investigator and sub-investigators for Study 003.
April 24, 1998	Serial No. 011: Submit change in protocol for studies 001, 002, 003 and addition of sub-investigators.
May 22, 1998	Discussion with Peter Dionne regarding urine and serology tests rather than cultures to obtain results from "atypical" organisms.
June 16, 1998	Serial No. 012: Request for end of Phase II meeting.

June 18, 1998	Serial No. 013: final study reports for two microbiology studies, one toxicology study and one clinical pharmacology study.
June 29, 1998	Discussion with FDA to schedule end of Phase II meeting and contents of briefing document.
July 7, 1998	Serial No. 014: submit 7 protocols across three indications: CAP (049, 012), ABS (009, 010) and cUTI (013, 014) and study synopses for studies 001 and 003.
July 8, 1998	Discussion with FDA regarding comparators chosen for CAP and uUTI studies. Safety, drug interaction, impairment of effect and labeling also discussed.
July 9, 1998	Fax to FDA containing Note to Reviewer mistakenly omitted from Serial No. 014.
July 13, 1998	Serial No. 015: submit 4 protocols for AECB (008, 068, 069, 070) and study synopsis for Study 002.
July 16, 1998	Serial No. 016: submit Briefing Document for end of Phase II meeting.
July 20, 1998	Discussion with Dr. Alivisatos regarding reporting of SAEs for Phase III trials.
July 27, 1998	Discussion with FDA regarding exporting of drug.
August 3, 1998	Serial No. 017: submit two final toxicology study reports.
August 3, 1998	Fax to FDA regarding revised definition of SAEs, amendment to protocol 014, revised synopsis for protocol 001 and definition of clinical success/failure.
August 4, 1998	Discussion with Dr. Alivisatos regarding protocols to be discussed during end of Phase II meeting.
August 6, 1998	Fax to FDA: microbiological methods for Dr. Alivisatos.

August 11, 1998	End of Phase II Meeting.
August 18, 1998	Fax to FDA regarding Iksan facility and use of 1 month stability data for drug substance.
August 21, 1998	Serial No. 018: CMC Amendment with fully updated drug substance section for the sesquihydrate form to be used in the Phase III trials. Information submitted for the tablet formulation and the various over-encapsulated comparators and matching placebos.
August 25, 1998	Serial No. 019: submit change in protocol for studies 012, 014 and 049.
September 4,1998	FDA Minutes for End of Phase II meeting (August 11, 1998)
September 11, 1998	Serial No. 020 Submit meeting minutes, overheads for the August 11 end of Phase II meeting and CMC sub-meeting.
September 15, 1998	Serial No. 021: Submit protocol amendment for Study 014 (new investigators), Dear Doctor letter regarding rashes and revised patient information and ICF.
September 17, 1998	Serial No. 022: Submit final clinical reports for studies 020 and 034, addendum to final report for Study 006.
September 17, 1998	Discussion with Dr. Schmuff (FDA Chemistry team leader) regarding inclusion of LG (Iksan) facility in the NDA with data from one drug substance batch with 1 month stability data versus the typical 3 months because the plant is currently under construction.
September 22, 1998	Serial No. 023: submit new investigators for Study 014.
September 23, 1998	Serial No. 024: submit SB's position piece on Laboratory Methods for Determination of Infection due to Atypical Pathogens for FDA's consideration, and product labeling for the diagnostic test kits that will be used.

September 28, 1998	Serial No. 025: submit change in protocols and new investigators for Studies 009 and 068.
September 29, 1998	Serial No. 026: submit new investigators for protocol 014.
October 6, 1998	Minutes of July 8, 1998 teleconference faxed by FDA.
October 7, 1998	Serial No. 027: submit new investigators for protocols 009 and 014.
October 12, 1998	Serial No. 028: submit protocol amendment for protocol 008.
October 20, 1998	Serial No. 029: submit new investigators for protocols 008, 009, 012, 014 and 049.
October 22, 1998	Fax to FDA: follow-up to End of Phase II meeting regarding work-up for adolescent patients with joint complaints, and lowering age limit to 16 on protocols 009 and 053.
October 27, 1998	Serial No. 030: submit new investigators for protocol 014.
October 28, 1998	Fax from FDA regarding proposed work-up for adolescent patients with joint complaints. Age limit of 16 years old OK; can proceed with study 009 and complete proposal for study 053.
October 29, 1998	Conversation with FDA regarding clinical plan to work-up joint complaints in adolescents, diagnostic tools for atypical pathogens, obtaining MART reports for trovafloxacin from FOI, and DDMAC issue of the "dual comparator" control regimen for the CAP study.
October 29, 1998	Fax to FDA regarding "dual comparator" control arm (protocol 012) and Zithromax® label.
October 29, 1998	Fax from FDA regarding additional comments from Biopharmaceutics reviewer referencing the End of Phase II Meeting.

October 30, 1998	Recommendation from FDA from pharmacologist to clarify data in report for study SB-265805/RSD-100NT5/1.
November 2, 1998	Serial No. 031: submit new European investigators for protocols 012 and 049.
November 4, 1998	Serial No. 032: submit new investigators for protocols 008, 014 and 068.
November 5, 1998	Serial No, 033: submit new investigators for protocols 009, 012 and 049.
November 6, 1998	Serial No. 034: submit Annual Report.
November 12, 1998	Serial No. 035: submit new investigators for protocols 008, 014 and 068
November 11, 1998	Serial No. 036: submit DMPK report (SB-265805?RSD-100TVN/1).
November 13, 1998	Serial No. 036: submit new European investigators for protocol 012.
November 16, 1998	Serial No. 038: submit new investigators for protocols 009, 012 and 049.
November 16, 1998	Fax to FDA: request to export drug
November 17, 1998	Serial No. 039: submit new investigators for protocols 008, 014 and 068.
November 17 & 18, 1998	Conversations with FDA regarding FOI requests for Trovan™ information.
November 18, 1998	Serial No. 040: submit new protocol 053: 320 or 640mg gemi once per day for 3 days versus 250mg cipro twice daily for 3 days for uUTI.
November 19, 1998	Fax from FDA requesting clarification of Nov 16 fax.

November 19, 1998	Serial No. 041: submit new investigators for protocols 008, 014 and 068.
November 20, 1998	Fax to FDA clarifying Nov16 fax—studies for which drug needs to be exported will not be under US IND.
November 23, 1998	Serial No. 042: submit protocol amendment for study 009 and submission of new protocol, 139.
November 24, 1998	Sent copy of previously submitted protocol 070 (Serial No. 015) for drug export request.
November 25, 1998	Response from USAN Council, acceptance of gemifloxacin mesylate as USAN.
December 3, 1998	Serial No. 043: submit change in protocol 014
December 8, 1998	Serial No. 044: submit new investigators for protocols 008, 014 and 068.
December 11, 1998	Serial No. 045: submit change in protocol 012 and new European investigators for protocols 012 and 049.
December 14, 1998	Serial No. 046: submit new investigators for protocols 008, 014 and 068.
December 16, 1998	Fax from FDA regarding recommendations for protocol 053.
December 17, 1998	Serial No. 047: submit new investigators for protocols 009, 012 and 049.
December 21, 1998	Serial No. 048: submit new investigators for protocols 008, 014 and 068.
December 23, 1998	Submit IND Safety Report (initial).
January 8, 1999	Serial No. 050: submit new investigators for protocols 008, 014 and 053.
January 11, 1999	Serial No. 051: submit new investigators for protocols 009, 012 and 049.

January 14, 1999	Authorization given by FDA to export drug to Estonia.
January 15, 1999	Serial No. 052: submit proprietary name FACTIVE™ and amendment to protocol 068.
January 19, 1999	Serial No. 053: submit new investigators for protocols 008 and 014.
January 20, 1999	Serial No. 054: submit new investigators for protocols 009, 049 and 068.
January 20, 1999	Serial No. 055: submit safety report (follow-up).
January 21, 1999	Serial No. 056: submit new investigators for protocols 008, 014 and 053.
January 29, 1999	Serial No. 057: submit DMPK, microbiology (*in vivo* and *in vitro*) and toxicology reports.
February 2, 1999	Serial No. 058: submit change in protocol and new investigators for protocol 008.
February 3, 1999	Serial No. 059: submit new investigators for protocols 009, 049, 053 and 068.
February 8, 1999	Serial No. 060: submit new protocol 079.
February 10, 1999	FDA Contact Report: discussion about IND for IV formulation.
February 12, 1999	Serial No. 061: submit new investigators for protocols 008, 053 and 068.
February 12, 1999	Fax from FDA with comments from the microbiologist regarding Serial No. 024 affecting the CAP protocols (012 and 049).
February 15, 1999	Serial No. 062: submit new investigators for protocols 014, 053 and 068.
February 16, 1999	Serial No. 063: submit new investigators for protocols 009, 012, 049 and 068.
February 17, 1999	SB fax to FDA listing reasons why cannot agree with microbiologists statements of February 12.

February 18, 1999	Discussion with FDA, reversing microbiologist's position taken on February 12, 1999.
February 19, 1999	Serial No. 064: submit safety report (initial).
February 22, 1999	Serial No. 065: submit change in protocol 049.
February 24, 1999	Serial No. 066: submit new investigators for protocols 008, 053 and 068.
February 26, 1999	Serial No. 067: submit new investigators for protocols 008, 009, 012, 049, 053 and 068.
February 26, 1999	Serial No. 068: submit safety report (initial).
March 8, 1999	Serial No, 069: submit safety report (follow-up).
March 9, 1999	Copy of most recent IB sent to Dr. Powers.
March 9, 1999	Fax from FDA requesting comments on possible effects of gender on the PK of gemifloxacin.
March 11, 1999	Serial No. 070: submit new investigators for protocols 008, 009, 012, 049, 053 and 068.
March 12, 1999	Correspondence from FDA containing questions and comments regarding protocol 049.
March 16, 1999	Serial No. 071: submit new investigators for protocols 012, 104, 049 and 068.
March 16, 1999	Serial No. 072: submit safety report (initial).
March 18, 1999	Serial No. 073: submit updated Investigator Brochure.
March 22, 1999	Serial No. 074: submit response to FDA request for information regarding protocol 079.
March 24, 1999	Serial No. 075: submit new protocol 080.

March 26, 1999	Serial No. 076: submit microbiology, DMPK and toxicology reports.
March 30, 1999	Serial No. 077: submit new investigators for protocols 008, 009, 014, 049 and 053.
March 31, 1999	Serial No. 078: submit new investigators for protocols 008, 009, 012, 014, 049, 053 and 068.
March 31, 1999	Serial No. 079: submit safety report (initial).
March 31, 1999	Serial No. 080: request for pre-NDA meeting.
April 6, 1999	Serial No. 081: submit new investigators for protocols 009, 012, 014, 049 and 053.
April 6, 1999	Fax from FDA regarding nomenclature, Factive accepted with concern.
April 7, 1999	Fax from FDA: OK to proceed with protocol 080.
April 7, 1999	Serial No. 082: response to FDA request for information regarding protocol 053.
April 8, 1999	FDA schedules pre-NDA meeting for May 27, 1999
April 11, 1999	Fax from FDA regarding issues for QT teleconference.
April 13, 1999	Serial No. 083: submit change in protocol 012.
April 15, 1999	Serial No. 084: submit new investigators for protocols 012, 014, 049 and 053.
April 16, 1999	Serial No. 085: submit new investigators for protocols 008, 012, 014, 049, 053 and 068.
April 16, 1999	Serial No. 086: submit safety report (follow-up).
April 20, 1999	Serial No. 087: submit DMPK report.
April 23, 1999	Serial No. 088: submit safety report (initial).

April 26, 1999	Serial No. 089: submit new investigators for protocols 012, 014, 049 and 053.
April 28, 1999	Serial No. 090: submit DMPK and chemistry report.
April 29, 1999	Serial No. 091: submit response to FDA request for information contains revised criteria for serologic diagnosis of *C. pneumoniae* infection.
April 29, 1999	Serial No. 092: submit pre-NDA briefing document.
May 7, 1999	Serial No. 093: submit new investigators for protocols 014, 053 and 068.
May 7, 1999	Serial No. 094: submit new investigators for protocols 008, 012, 014 and 049.
May 7, 1999	Serial No. 095: submit final clinical study report for protocol 003.
May 7, 1999	Serial No. 096: submit new protocol and investigator for Study 126.
May 12, 1999	Serial No. 097: request for pre-IND/pre-Phase III meeting (for IV formulation).
May 12, 1999	Correspondence from FDA authorizing export of investigational drug to Mexico.
May 12, 1999	Fax from FDA regarding diagnosis of atypical organisms.
May 12, 1999	Serial No. 098: submit DMPK reports.
May 18, 1999	Serial No. 099: submit safety report (initial).
May 20, 1999	Serial No. 100: submit change in protocol 014.
May 20, 1999	SB fax to FDA regarding electronic submission plans for NDA.
May 20, 1999	FDA fax comments regarding questions in pre-NDA briefing document.

May 21, 1999	Serial No. 101: submit new investigators for protocols 008, 049 and 068.
May 25, 1999	SB faxed responses to comments received from FDA on May 20, 1999.
May 26, 1999	Serial No. 102: submit DMPK and toxicology reports.
May 27, 1999	Pre-NDA Meeting.
June 1, 1999	Fax from FDA: OK to proceed with protocol 126.
June 3, 1999	Serial No. 103: submit new investigators for protocols 008, 014, 053 and 126.
June 10, 1999	Fax from FDA scheduling meeting for IV formulation on July 13, 1999.
June 11, 1999	Serial No. 104: submit end of Phase II briefing document for IV meeting.
June 14, 1999	Serial No. 105: submit new investigators for protocols 008, 009, 049, 053 and 126.
June 15, 1999	Serial No. 106: submit change in protocol 068.
June 15, 1999	SB fax to FDA regarding IND for IV formulation.
June 22, 1999	Serial No. 107: DMPK and microbiology reports.
June 22, 1999	Fax from FDA regarding filing of separate IND for IV formulation and clinical reports to be submitted in NDA.
June 28, 1999	Serial No. 108: Submit preclinicial safety report (initial) regarding results of rat pre- and postnatal reproductive toxicology.
June 30, 1999	Serial No. 109: submit new investigators for protocols 049, 068 and126.
June 30, 1999	Serial No. 110: submit new investigators for protocols 008, 012, 014, 049, 053, 068 and 126.

June 30, 1999	Fax from FDA with comments from microbiologist regarding Serial No. 057.
July 1, 1999	Serial No. 111: submit microbiology reports.
July 2, 1999	FDA teleconference regarding the clastogenic findings from *in vivo* intravenous rat micronucleus study.
July 2, 1999	Serial No. 112: submit final clinical study reports for protocols 019, 021, 022, 023 and 084.
July 6, 1999	FDA contact report trying to schedule telecon with Dr. Ellis to discuss rat clastogenicity (Serial No. 113).
July 8, 1999	FDA contact report postponing July 13 IV meeting and requested telecon with Dr. Ellis.
July 14, 1999	Discussion with Peter Dionne regarding microbiology reports submitted july 1 (Serial No. 111).
July 16, 1999	Serial No. 113: submit preclinical safety report for rat micronucleus test results.
July 16, 1999	FDA contact report postponing IV meeting and results of *in vivo* rat micronucleus test.
July 22, 1999	Serial No. 114: submit new investigators for protocols 014 and 049.
July 26, 1999	Fax from FDA granting official acceptance of FACTIVE™ name.
July 27, 1999	Serial No. 115: submit meeting minutes for pre-NDA meeting held on May 27.
July 28, 1999	Serial No. 116: response to FDA questions raised by Peter Dionne.
August 5, 1999	Serial No. 117: submit new investigators for protocols 009, 068 and 126.
August 12, 1999	Serial No. 118: submit new investigators for protocols 008, 009, 012, 014, 049, 053 and 068.
August 16, 1999	SB faxed summary of protocol 082 results to Division.
August 16, 1999	Serial No 119: submit new investigators for protocols 008, 012, 014, 049, 053, 068 and 126.

August 16, 1999	FDA response to questions in the briefing document for IV formulation meeting scheduled for August 31, 1999.
August 18, 1999	Serial No. 120: submit end of Phase II briefing document update for IV formulation.
August 19, 1999	Serial No. 121: submit safety report (follow-up).
August 23, 1999	Serial No. 122: submit new investigators for protocols 009, 012, 068 and 126.
August 25, 1999	Fax from FDA with May 27/pre-NDA meeting minutes.
August 31, 1999	Pre-IND meeting for IV formulation.
September 2, 1999	Questions faxed to Division regarding contents and structure of NDA.
September 10, 1999	FDA response to Sept 2 fax.
September 14, 1999	Serial No. 123: submit changes to investigator information previously submitted for protocols 008, 009, 012, 014, 049, 053 and 068.
September 24, 1999	Serial No. 124: submit amendment to CMC data.
September 23, 1999	Serial No. 125: submit new investigators and changes to current investigator information for protocol 126.
September 27, 1999	Serial No. 126: submit results of further investigations of the *in vivo* clastogenic potential of gemi.
September 29, 1999	Serial No. 127: submit update for items discussed during the EoPII meeting in August 1998. Items include: starting materials for drug substance, process improvement, additional sites for manufacture of drug substance, biostudies and dissolution and other misc. items.
October 6, 1999	Serial No. 128: request for FDA opinion regarding design of protocol 111 for IV formulation.

October 6, 1999	Serial No. 129: submit safety report (initial).
October 12, 1999	SB faxed confirmation of October 14 telecon to ascertain which type of data display FDA would find most appropriate for the presentation of plasma concentration results. Two examples faxed.
October 14, 1999	Teleconference with FDA regarding plasma concentration data display.
October 15, 1999	Serial No. 130: submit investigator revisions for protocols 068 and 126.
October 18, 1999	Serial No. 131: submit termination of study 126.
October 22, 1999	Teleconference with FDA regarding Study 111.
November 2, 1999	FDA faxed minutes of October 22 teleconference.
November 5, 1999	Serial No. 132: submit Annual Report
November 11, 1999	Serial No. 133: submit new protocol 105.
November 15, 1999	Submit Gemifloxacin Mesylate DMF 14524.
November 17, 1999	Serial No. 134: submit new protocol 206.
November 18, 1999	Serial No. 135: submit new protocol 186.
November 23, 1999	Serial No. 136: submit new protocol 207.
November 30, 1999	FDA Contact Report: Dr. Powers requested copy of a CFR for protocol 105.
December 1, 1999	Fax to FDA with intent of study 105.
December 2, 1999	Fax from FDA with questions about recently submitted protocols.

December 2, 1999	Fax from FDA: OK to proceed with protocol 105.
December 2, 1999	Serial No. 138: submit response to request for further information for protocol 105.
December 6, 1999	SB faxed to FDA intent and start dates of protocols 185, 186, 206 and 207.
December 6, 1999	Fax from FDA: OK to proceed with protocol 185.
December 16, 1999	Serial No. 139: submit new protocol 112 and request for FDA opinion of protocol.
December 29, 1999	Serial No. 140: submit response to FDA request for information regarding protocol 105.
January 4, 2000	Serial No. 141: submit new investigators for protocols 112, 185 and 206.
January 7, 2000	Serial No. 142: Submit request for FDA opinion on revised protocol 111 (IV study).
January 14, 2000	Serial No. 143: response to FDA comments on protocols 105, 186, 206 and 207.
January 14, 2000	Serial No. 144: submit new investigators for protocols 105 and 185.
January 14, 2000	Serial No. 145: submit new investigators for protocols 186 and 206.
January 17, 2000	Serial No.146: submit new investigators for protocol 207.
January 18, 2000	Serial No. 147: submit amendment to protocol 185.
January 26, 2000	Serial No. 148: response to FDA comments on protocol 185.
January 21, 2000	Serial No. 149: response to FDA comments on protocol 112.
February 3, 2000	Serial No. 150: submit new investigators for protocols 112, 185 and 206.
February 4, 2000	Serial No. 151: submit new investigators for protocol 112.

February 7, 2000	E-mail request from FDA for American Thoracic Society (ATS) statement on obtaining measurements of FEV1.
February 14, 2000	SB sends publication with ATS statement to FDA electronically.
February 16, 2000	Serial No. 152: submit new investigators and revised investigator information for protocols 008, 009, 012, 014, 049, 053, 068 and 126.
February 16, 2000	Serial No. 153: official submission of ATS statement.
February 25, 2000	Serial No. 154: submit new investigators for protocols 105, 206 and 207.
February 28, 2000	Serial No. 155: submit new investigators for protocol 185.
February 28, 2000	Serial No. 156: submit response to FDA faxed comments for protocol 111.
February 28, 2000	Serial No. 157: submit response to FDA comments on protocol 105.
February 29, 2000	Serial No. 158: submit new investigators for protocol 112.
March 1, 2000	Fax from FDA: comments on protocol 111.
March 2, 2000	Serial No. 159: submit new investigators for protocols 105, 112, 185 and 206.
March 2, 2000	Serial No. 160: submit new investigators for protocols 112 and 186.
March 6, 2000	Serial No. 161: submit investigator information revisions for protocols 008, 009, 012, 014, 049 and 068.
March 7, 2000	Serial No. 162: submit response to FDA comments on protocol 112.
March 14, 2000	Serial No. 163: submit new investigators and investigator revisions for protocols 112, 185, 186 and 207.
March 16, 2000	Serial No. 164: submit new investigators for protocols 105, 112, 185 and 206.

March 28, 2000	Serial No. 165: submit new investigators and investigator revisions for protocols 105, 112, 185, 186 and 207.
April 13, 2000	Serial No. 166: submit safety report (initial).
April 14, 2000	Serial No. 167: submit amendment for protocol 112.
April 18, 2000	Serial No. 168: submit new investigators and investigator revisions for protocols 105, 112, 185 and 207.
April 19, 2000	Serial No. 169: submit new investigators and investigator revisions for protocols 009, 014, 049 and 126.
April 19, 2000	Serial No. 170: submit amendment for protocol 139.
April 26, 2000	Serial No. 171: submit amendment for protocol 206.
Apirl 26, 2000	Serial No. 172: submit new investigators and investigator revisions for protocols 105, 112 and 206.
April 27, 2000	Serial No. 173: submit new investigators and investigator revisions for protocols 112, 185, 186 and 207.
May 9, 2000	FDA fax on evaluation of Acute Sinusitis Patients.
May 11, 2000	Serial No. 174: submit revised IB (5^{th} edition).
May 22, 2000	Serial No. 175: submit response to FDA questions regarding protocol 112 and request for a meeting with FDA to discuss protocols 112 and 139.
May 24, 2000	Serial No. 176: submit new investigators and investigator revisions for protocols 105, 112, 185, 186 and 207.
May 31, 2000	Serial No. 177: submit new investigator and investigator revisions for protocols 112, 185 and 206.

June 5, 2000	FDA fax scheduling meeting to discuss protocols 112 and 139 on June 28, 2000 (Type C meeting).
June 9, 2000	Serial No. 178: submit new investigators and investigator revisions for protocol 112.
June 13, 2000	Serial No. 179: request to postpone June 28 meeting.
June 27, 2000	Serial No. 180: submit safety report (follow-up).
June 30, 2000	Serial No. 181: submit new investigators and investigator revisions for protocols 112, 185 and 206.
July 6, 2000	Serial No. 182: submit amendment for protocol 080.
July 7, 2000	Serial No. 183: submit CMC amendment to extend shelf life from 24 to 36 months.
July 13, 2000	Serial No. 184: submit new investigators and investigator revisions for protocols 112 and 185.
July 18, 2000	Submit a revised version of the report for Study 037 (Serial No. 185) entitled "An open, randomized, two-way crossover study to assess the penetration of gemifloxacin at steady-state into bronchial mucosa and bronchoalveolar lavage fluid in healthy volunteers".
July 31, 2000	Serial No. 186: submit new protocol 212.
August 1, 2000	Serial No. 187: submit safety report (initial).
August 3, 2000	Serial No. 188: submit request for FDA meeting (rescheduling of meeting to discuss protocols 112 and 139.)
August 10, 2000	Serial No. 189: submit new investigators and investigator revisions for protocols 112 and 206.
August 11, 2000	Serial No. 190: submit amendment and modification of protocol 105.
August 23, 2000	Serial No. 191: submit safety report (follow-up).

August 24, 2000	Fax from FDA: OK to proceed with protocol 212.
August 25, 2000	Serial No. 192: submit new investigators and investigator revisions for protocol 112.
August 31, 2000	Serial No. 194: submit new protocol 287.
September 8, 2000	FDA Correspondence: schedule Type C meeting to discuss protocols 112 and 139 on November 7, 2000.
September 13, 2000	Serial No. 195: submit new investigators and investigator revisions for protocols 112 and 212.
September 15, 2000	Serial No. 196: submit new investigators and investigator revisions for protocols 112 and 287.
September 15, 2000	Serial No. 197: submit response to FDA comments on protocol 212.
September 29, 2000	Serial No. 198: submit new investigators and investigator revisions for protocols 112, 185, 212 and 287.
October 8, 2000	Fax from FDA regarding concerns with protocols 287 and 107.
October 9, 2000	Serial No. 199: submit end of Phase II (EoPII) briefing document.
October 12, 2000	Serial No. 200: submit new investigators and investigator revisions for protocols 112, 212 and 287.
October 18, 2000	Serial No. 201: submit new investigators and investigator revisions for protocols 212 and 287.
October 27, 2000	Serial No. 202: submit Annual Report
November 14, 2000	Serial No. 203: submit new investigators and investigator revisions for protocols 112, 206, 212 and 287.
November 22, 2000	Serial No. 204: submit DMPK report

November 30, 2000	Serial No. 205: submit new investigators for protocols 185, 186, 212 and 287.
	Serial No. 206 (N/A)
January 10, 2001	Serial No. 207: submit amendment and new investigators for protocol 287.
January 22, 2001	SB request to export drug to China.
January 26, 2001	Serial No. 208: submit amendment and new investigators for protocol 287.
January 29, 2001	Serial No. 209: submit amendment and investigator revisions for protocol 212.
January 30, 2001	Serial No. 210: submit new protocol 333.
February 26, 2001	Serial No. 211: submit new investigators for protocol 333.
February 26, 2001	Fax from FDA regarding protocol 333, OK to proceed, but have comments.
March 1, 2001	Serial No. 212: response to request for information on patient with possible pustular dermatosis.
March 12, 2001	Serial No. 213: investigator revisions for protocols 112, 212 and 287; new investigators for protocol 333.
April 17, 2001	Serial No. 214: submit DMPK report
April 17, 2001	Serial No. 215: submit new protocol 344.
April 19, 2001	Serial No. 216: submit investigator revisions for protocols 112, 212 and 287; new investigators for protocol 333.
May 7, 2001	SB fax to FDA with safety report (initial)
May 8, 2001	Fax from FDA: OK to proceed with protocol 344, but have comments.

May 11, 2001	Serial No. 217: submit official safety report (initial), faxed on May 7, 2000.
May 22, 2001	Serial No. 218: submit investigator revisions for protocols 112, 287 and 333; new investigators for protocol 344.
June 7, 2001	Serial No. 219: submit final clinical study report for protocol 185.
June 8, 2001	Serial No. 220: submit safety report (initial).
June 11, 2001	Serial No. 221: submit amendment and new investigators for protocol 344.
June 14, 2001	Serial No. 222: submit new investigators and investigator revisions for protocols 287, 333 and 344.
June 22, 2001	Serial No. 223: submit final clinical study report for protocol 077.
June 22, 2001	Serial No. 224: submit final clinical study report for protocol 062.
June 27, 2001	Serial No. 225: submit final clinical study report for protocol 059.
June 27, 2001	Serial No. 226: submit safety report (initial).
July 5, 2001	Serial No. 227: submit final clinical study report for protocol 036.
July 6, 2001	Serial No. 228: submit final clinical study report for protocol 033.
July 13, 2001	Serial No. 229: submit new investigators and investigator revisions for protocols: 112, 212, 287, 333 and 344.
July 20, 2001	Serial No. 230: submit safety report (follow-up)
August 2, 2001	Serial No. 231: submit new investigators and investigator revisions for protocols 287, 333 and 344.
August 9, 2001	Serial No. 232: submit DMPK reports.

August 2001	Serial No. 233: to be clarified w/ GSK.
August 22, 2001	Serial No. 234: submit DMPK reports.
September 10, 2001	Serial No. 235: submit new investigators and investigator revisions for protocols 287, 333 and 344.
September 12, 2001	Serial No. 236: submit new investigators and investigator revisions for protocols 287 and 344.
September 17, 2001	Serial No. 237: submit new investigators for protocol 333.
September 19, 2001	Serial No. 238: submit DMPK report.
September 27, 2001	Serial No. 239: new investigators and investigator revisions for protocol 344.
October 22, 2001	Serial No. 240: submit new investigators and investigator revisions for protocols 287 and 333.
October 25, 2001	Serial No. 241: submit safety report (follow-up).
October 30 ,2001	Serial No. 242: submit new investigators and investigator revisions for protocols 185, 287, 333 and 344.
November 6, 2001	Serial No. 243: submit Annual Report
February 4, 2002	Serial No. 244: submit new investigators for protocols 287 and 333.
February 28, 2002	Serial No. 245: submit new investigators for protocols 287 and 333.
April 4, 2002	Serial No. 246: new investigators and investigator revisions for protocols 287, 333 and 344.
April 22, 2002	Serial No. 247: submit new investigators and investigator revisions for protocols 287 and 333.
June 5, 2002	Serial No. 248: submit new investigators and investigator revisions for protocols 287 and 333.

June 26, 2002	Serial No. 249: submit nonclinical study reports: SB-265805/RSD101MCG/1, SB-265805/RSD-101MGD/1, General/RSD-1018F1/1 and SB-265805/RSD-101BT0/2.
July 11, 2002	Serial No. 250: submit nonclinical study reports: SB-265805/RSD-101GVB/1, SB-265805/RSD-101MG9/1, SB-265805/RSD-101MGB/1, SB-265805/RSD-101N65/2 and SB-265805/RSD-101NB3/1.
July 25, 2002	Serial No. 251: submit response to FDA request for patient profiles and datasets for study 185.
July 29, 2002	Serial No. 252: submit response to FDA request for specific listings for study 185.
August 5, 2002	Serial No. 253: submit abridged clinical study reports for protocols 001, 003, 008, 009, 010, 013, 049, 053, 067 and 068.
August 6, 2002	Serial No. 254: submit 34 microbiology reports.
August 13, 2002	Serial No. 255: submit DMPK and pharmacology reports.
August 16, 2002	Serial no. 256: submit final clinical study reports for protocols 024, 056, 114 and 344.
August 20, 2002	Serial No. 257: submit a microbiology report, SB-265805/RSD-101TRW/1.
August 22, 2002	Serial No. 258: submit response to FDA request for information regarding study 185.
August 23, 2002	Serial No. 259: submit response to FDA request for CRFs for protocol 185.
August 29, 2002	Serial No. 260: submit revised investigator information for protocol 287.
September 13, 2002	Serial No. 261: submit clinical study reports for protocols 105, 112, 139, 207 and 212.

September 17, 2002	Serial No. 262: submit missing Vol 17 of 25 for Serial No. 261.
September 24, 2002	Serial No. 263: submit IND transfer from GSK to LGLS.
September 26, 2002	Serial No. 264: submit acceptance of IND transfer and transfer of obligations to PAREXEL.
October 21, 2002	Serial No. 265: submit response to request for additional CRFs for study 185.
December 19, 2002	Serial No. 266: submit Annual Report.
December 31, 2002	Submit clinical reports for studies 106, 107, 111 under IND No. 60,132.
January 3, 2003	Serial No. 267: submit clinical study reports for protocols 303 and 333.
April 8, 2003	Serial No. 268: submit clinical pharmacology reports for protocols 044, 060, 062, 075, 079, 080, 245, 249 and 250.

NDA Chronology

December 15, 1999	NDA 21-158 submitted to FDA.
December 27, 1999	Acknowledgement from FDA receiving the NDA package for review.
December 28, 1999	Request for statistical plan change clarifications in studies SB-265805/013 and SB-265805/014.
December 30, 1999	Request for listing of duration of therapy in studies SB-265805/013 and SB-265805/014.
January 4, 2000	Response to request for word document files for the reports of studies SB-265805/013 and SB-265805/014.
January 6, 2000	Response to request for clarification/information regarding clinical studies SB-265805/013 and SB-265805/014.
January 10, 2000	Submit Field Copy of NDA 21-158.

January 18, 2000	Response to request for patient profiles (CRTs) for the clinical trials contained in NDA 21-158.
January 21, 2000	Request for 8-month safety update.
February 8, 2000	Fileability of NDA confirmed by FDA.
February 17, 2000	Request for additional regression analyses comparing plasma drug Cmax to change in QTc, and plasma drug concentration to time of maximal change in QTc.
February 18, 2000	Response to request regarding FDA's proposed inspection of the investigators.
February 23, 2000	Request for samples (Drug Product, Drug Substance) to perform methods validation.
March 2, 2000	Response to FDA request for x-ray assessment reports for the patients in studies 009, 010, 011, 012, and 049.
March 7, 2000	Response to "Method Validation Letter" dated February 23, 2000. Submit copies of specification, methods and validations detailed in LG Chemical's DMF 14524 for Gemifloxacin Mesylate.
March 7, 2000	Response to request letter dated February 17, 2000.
March 13, 2000	Pre-announcement of PAI (Pre-Approval Inspection) for primary manufacturing site located at Iksan, Korea.
March 22, 2000	Response to provide accommodation details for PAI of Iksan site.
March 23, 2000	Response to request for ECG data.
March 31, 2000	Response to request for a full waiver for conducting pediatric studies.
April 27, 2000	FDA notice of non-approval for Acute Pyelonephritis indication.
May 1~3, 2000	PAI of Iksan site.

May 19, 2000	Submit "coming soon" campaign for Factive® logo.
May 30, 2000	Response on Factive®'s lack of efficacy data in acute pyelonephritis referenced in the letter dated April 27, 2000.
June 1, 2000	Request for additional information related to CAP studies.
June 15, 20, 27, 2000	Responses to request for information regarding CAP studies.
June 27, 2000	Amendment to Pending NDA 21-158: current and correct analytical method "Determination of Impurities and Degradations for SB-265805-S by HPLC".
July 21, 2000	Amendment to Pending Application: pharmacokinetic data for comparator drug, trovafloxacin, in study 037 and revision of macrophage concentrations of gemifloxacin.
August 8, 2000	Request for additional information regarding NDA submission.
August 10, 2000	Provided comments on the microbiology section of the proposed labeling.
August 14, 2000	Submit 8-month Safety Update.
August 15, 2000	Response to request dated August 8, 2000.
August 15, 2000	Request for supporting data used in March 7th submission on QTc issues.
August 18, 2000	Response to request dated August 15, 2000.
August 24, 2000	Response to request for clarification and/or additional information on some of the data from the CAP, ABS and AECB clinical trials.

September 1, 2000	Submit revised microbiology section of the labeling in accordance with FDA comments dated August 10, 2000.
September 1, 2000	EIR (Establishment Inspection Report) issued for Iksan PAI.
September 8, 2000	Request to export drug to the People's Republic of China to be used as clinical trial supplies.
September 26, 29, 2000	Requests (I) for additional safety information.
September 26, 28, 2000	Response on safety information.
October 2, 10, 2000	Request (II) for additional safety information.
October 9, 2000	Response to request for statistical appendices for the clinical studies.
October 11, 16, 17, 2000	Responses to additional questions on rash.
October 19, 2000	Submit previous agreements with the Division on packaging.
October 25, 2000	Receive FDA labeling counterproposal.
October 31, 2000	Submit Briefing Document for November 7, 2000 Meeting to discuss FDA's concerns.
November 3, 2000	Response to request for additional information on NDA 21-158.
November 7, 2000	Face to Face Meeting to discuss safety concerns (rash, hepatotoxicity, QT prolongation).
November 21, 2000	Response to request for additional information on rash issues.
November 24, 2000	Request for a meeting w/ Director of CDER.
November 27, 2000	Response to request for "benefits" summary.

November 28, 2000	Response to request for letters from consultants who were mentioned in October 31, 2000 meeting package.
December 4, 2000	Request for additional information regarding CMC.
December 7, 2000	Comments provided on FDA Meeting Minutes regarding November 7, 2000 Meeting.
December 8, 2000	Response to CMC deficiency questions.
December 15, 2000	Non-Approvable Letter for NDA 21-158.
December 22, 2000	Notice for a meeting delay regarding action letter
January 12, 2001	Request for a meeting to discuss clinical safety of Factive®
January 19, 2001	FDA confirmation of a type A meeting on February 22, 2001
February 6, 2001	Submit Briefing Document for February 22, 2001 Meeting.
February 22, 2001	Face to Face Meeting on Resubmission Proposal
March 9, 2001	Submit Minutes of the February 22, 2001 Meeting.
March 16, 2001	Request for additional information on rash.
April 4, 2001	Response to request for a reference to support the statistical methodology proposed to be used in the analysis of the 'rash' data to be acquired from clinical studies 265805/344 and 265805/345.
April 10, 2001	Response to request for tabular displays of rash data.
April 12, 2001	Submit 2nd Safety Update DAP (Dossier Analysis Plan).
April 24, 2001	Receipt of User Fee ID Assignment.

April 25 ~ October 17, 2001	Conduct study 344 to address FDA concerns: A two part study to characterize the histology and clinical features of rash associated with gemifloxacin and to assess the potential for cross-sensitization to another quinolone in healthy female volunteers.
June 5, 2001	Response to request for further rash analysis data.
June 14, 2001	Submit NDA 21-376 for 5-day ABS (Acute Bacterial Sinusitis).
July 19, 2001	FDA notice that NDA 21-376 cannot receive an "Approval" action without the additional safety data relating to rash.
August 3, 2001	Request for teleconference regarding submission of additional PRSP (penicillin-resistant *S. pneumoniae*) data.
August 14, 2001	Request for iv program clarifications and CRTs/CRFs for study 344.
August 17, 2001	Request for Interim Study Report for Study 287.
August 21, 2001	Request for 18-month Safety Update without Dr. Passage's Date, study 186 report revisions without Dr. Passage's data.
August 23, 2001	Amendment to NDA 21-376: revised key efficacy and safety tables for study 265805/206.
September 4, 2001	Response to request for clinical documents regarding FDA inspection of the investigators.
October 18, 2001	Amendment to NDA 21-376: revised study 186 key efficacy and safety tables, revised ISS key safety tables.
January 8, 2002	Request for a meeting to discuss approvability of NDA 21-158 and 21-376 based on new data for rash and CAP (community-acquired pneumonia) studies.

January 18, 2002	Acknowledgement of February 27, 2002 Face to Face Meeting.
February 12, 2002	Submit Briefing Document for February 27, 2002 Meeting.
February 22, 2002	Submit DMF Annual Update.
February 27, 2002	Type A Face to Face Meeting regarding NDA Resubmission.
April 9, 2002	GlaxoSmithKline (GSK) termination letter to LG Life Sciences.
April 12, 2002	Non-Approvable Letter for NDA 21-376.
April 18, 2002	Notification of Intent to Amend Application NDA 21-376.
May 31, 2002	LG/Parexel Agreement for Services signed. Parexel to act as U.S. agent.
July 2, 2002	Teleconference (FDA/GSK/LG Life Sciences/Parexel) to discuss Factive® transfer and resubmission.
August 23, 2002	LG/GeneSoft Pharmaceuticals Memorandum of Understanding signed. GeneSoft Pharmaceuticals to be U.S. commercial partner.
September 11, 2002	Request for additional information on study 185 and CRFs for patients with *Legionella pneumophila*.
September 26, 2002	Transfer of IND/NDA sponsorship from GlaxoSmithKline to LG Life Sciences, Parexel as U.S. Agent.
October 4, 2002	Resubmission to NDA 21-158 filed.
October 14, 2002	Submit AECB efficacy data: individual study reports for the new studies 105, 112, 139, 207, 212 and 298.
October 14, 2002	LG/GSK Termination Agreement signed.

October 21, 2002	Reponse to request dated September 11, 2002.
October 22, 2002	LG/GeneSoft License and Option Agreement signed.
October 23, 2002	Request for select study 287 Case Report Tabulations missing from October 4, 2002 resubmission.
October 31, 2002	Teleconference to discuss updating of safety information.
November 6, 2002	Request for additional data and analyses that pertain to studies 303, 333 and 287 as well as the CAP-IV studies 106, 107, 111.
November 8, 2002	Request for table containing Class 4/5 patients in all studies in the resubmission except study 185.
November 25, 2002	Acknowledgement of October 4, 2002 resubmission as a complete, class 2 response to December 15, 2000 action letter.
November 25, 2002	Teleconference to discuss submission timeline of study reports, possibility of further safety update and face to face meeting.
November 27, 2002	Request for information regarding inspection of a site that participated in study 344.
December 2, 2002	Receive FDA letter outlined procedures for the Anti-Infective Drugs Advisory Committee Meeting scheduled for March 4, 2003.
December 6, 2002	Request for follow-up information for two sudden cardiac deaths in studies 106 and 112.
December 9, 2002	Response to request for patient listings, rash data and investigator information for protocol SB 265805/344 stated in the November 27 letter.
December 12, 2002	Request for investigator list and Vol 1.1 of the Resubmission.
December 16, 2002	Request for pregnancy outcomes for patients in study 344.

December 20, 2002	Response to requests dated December 9, 2002 and December 16, 2002.
December 23, 2003	Request for additional information regarding safety update.
December 30, 2002	Submit Briefing Package for January 22, 2003 Teleconference.
December 30, 2002	Submit CMC amendment.
December 31, 2002	Request for additional information regarding PRSP and CAP data.
January 6, 2003	Division meeting to discuss Factive® Resubmission.
January 7, 2003	Request for additional information regarding extent of exposure table for all *S. pneumoniae* patients.
January 13, 2003	Request for additional information from Biopharmaceutics and Clinical Pharmacology reviewers.
January 15, 2003	Federal Register notice of March 4, 2003 meeting of the Anti-Infective Drugs Advisory Committee.
January 16, 2003	Response to request dated December 31, 2002.
January 22, 2003	Request for a table summarizing rates of rash in all AECB studies by sex, age and duration of treatment received.
January 22, 2003	Teleconference to discuss briefing document for March 4 Advisory Committee Meeting.
January 24, 2003	Response to request dated January 13, 2003.
January 27, 2003	Request for additional hepatotoxicity data.
January 27, 2003	Request for changes to Advisory Committee Background Package.

January 30, 2003	Submit Background Package for Advisory Committee Meeting.
February 3, 2003	Request for additional information regarding patients who received macrolides in the CAP studies.
February 4, 2003	Request for a table listing number of patients with *S. pneumoniae* and PRSP.
February 11, 2003	Response to requests dated January 7, 2003, February 3, 2003, February 4, 2003, January 22, 2003, and January 27, 2003.
February 13, 2003	Receive FDA Background Package and Advisory Committee List.
February 25, 2003	Face to Face Meeting to discuss about FDA Advisory Committee Meeting preparation.
March 4, 2003	FDA Anti-Infective Drugs Advisory Committee Meeting on Factive®.
March 7, 2003	Request for analysis of occurrence of rash by age and gender of subjects.
March 7, 2003	Teleconference to discuss next steps after Advisory Committee Meeting.
March 12, 2003	Submit revised labeling and foil packs.
March 17, 2003	Request for a listing of subjects diagnosed with *S. pneumoniae* demonstrating tetracycline and TMP-SMX resistance.
March 21, 2003	Teleconference to discuss tetracycline/TMP-SMX use affecting rash.
March 25, 2003	Teleconference regarding labels for cartons and blister foils.
March 26, 2003	Receive comments from Pharmacology/Toxicology reviewer.
March 27, 2003	Response to requests dated March 7, 2003 and March 17, 2003.

March 27, 2003	Teleconference regarding post-marketing pharmacovigilance plan.
March 28, 2003	Submit written confirmation of the agreements reached during March 27, 2003 teleconference.
March 28, 2003	Submit revised labels for cartons and blister foils agreed during March 25, 2003 teleconference.
March 31, 2003	Teleconference to discuss options for submitting additional information for the multi-drug resistant *S. pneumoniae* (MDRSP) claim.
April 1, 2003	Submit Patent Information.
April 2, 2003	Teleconference regarding carton labels and labeling discussions.
April 3, 2003	Submit revised packaging and the final draft labeling.
April 4, 2003	Approval Letter: Factive® granted approval for commercial marketing in U.S.